IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BIOGEN IDEC MA INC., Plaintiff, v. JAPANESE FOUNDATION FOR CANCER RESEARCH, et al., Defendants.	No. 1:13-cv-13061-FDS

REPLY IN FURTHER SUPPORT OF JFCR'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

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I. INTRODUCTION

Japanese Foundation for Cancer Research ("JFCR") demonstrated in its opening memorandum that the America Invents Act ("AIA") eliminated district court review of patent interferences commenced on or after September 16, 2012. Biogen resists this conclusion, arguing that under § 3(n)(1) of the AIA, the elimination of district court review does not apply to the interference at issue here. Biogen misreads the plain text of § 3(n)(1) and, moreover, cannot explain the fact that its reading would render other sections of the AIA superfluous. Biogen's argument must therefore be rejected, and this action dismissed for lack of subject-matter jurisdiction.

II. ARGUMENT

A. There Is No Longer Any Statutory Basis for Subject Matter Jurisdiction Under 35 U.S.C. § 146

As explained in JFCR's opening brief, the AIA replaced the "first-to-invent" patent system with a "first-inventor-to-file" system. Opening Br. at 6. This system prospectively eliminated patent interferences, which are meant to determine the first inventor of a claimed invention. AIA § 3(j), 125 Stat. 290-291.[1] The AIA's first-inventor-to-file system went into effect on March 16, 2013; however, the AIA explicitly stated that interferences would continue to be declared with respect to patents and patent applications filed *before* March 16, 2013. AIA § 3(n)(2)(A), 125 Stat. 293. Thus, the Patent and Trademark Office ("PTO") declared an interference on July 16, 2013, between the Sugano '757 Application and the Fiers '843 Application, both of which were filed before March 16, 2013. Opening Br. at 7.

[1] An appendix of relevant statutory provisions is attached hereto as Appendix A.

In addition to prospectively abolishing patent interferences, the AIA amended 35 U.S.C. §§ 141 and 146, which had previously provided for two avenues of review for decisions on interferences: (1) by appeal to the Federal Circuit, or (2) by a civil action in a district court. The new 35 U.S.C. § 146 deleted each reference to "interferences" and substituted references to "derivations," which are new proceedings relevant to the first-inventor-to-file regime. The AIA also abolished the Board of Patent Appeals and Interferences, which had decided interferences in the first instance, and replaced it with a new entity called the Patent Trial and Appeal Board ("Board"), which handled derivations. AIA § 7(a)(1), 125 Stat. 313. Thus – as Biogen does not dispute – the current version of 35 U.S.C. § 146, which once governed review of decisions in interferences, by its terms no longer relates to interferences at all.

Because the new version of § 146 eliminated all review of interferences, even though interferences continued to exist, Congress also enacted a new section, AIA § 6(f)(3)(C), 125 Stat. 311, to fill the gap. Section 6(f)(3)(C) expressly extended the amended versions of 35 U.S.C. §§ 141 and 146 to apply to interferences "commenced before" and "pending on" September 16, 2012. Thus, such interferences could be reviewed both in a district court or in the Federal Circuit. In an apparent oversight, however, Congress provided no route for review at all for interferences declared after September 16, 2012, such as the '939 Interference at issue here. Congress promptly fixed this error in the Leahy-Smith America Invents Technical Corrections Act, which went into effect on January 13, 2013, and was intended to "correct and improve" the AIA. Technical Corrections–Leahy-Smith America Invents Act, Pub L. No. 112-274, 126 Stat. 2458. Section 1(k)(3) of the Technical Corrections Act provided that "the provisions of section 6 and 141 of title 35 *[establishing the Board and providing for appeals to the Federal Circuit]*, United States Code, and section 1295(a)(4)(A) of title 28 *[providing for exclusive Federal*

Circuit jurisdiction over appeals from certain proceedings in the Board], United States Code, as in effect on September 15, 2012, shall apply to interference proceedings that are declared after September 15, 2012. . . ." Although this provision clearly established Federal Circuit review of decisions on interferences declared after September 15, 2012, it made no reference whatsoever to review in the district courts.

Under this coherent and clear statutory scheme, Biogen's only route of review for the decision below was in the Federal Circuit. However, Biogen elected not to appeal to the Federal Circuit (Compl. ¶ 27). In an attempt to evade the consequences of its own actions, Biogen constructs a new interpretation of the AIA and Technical Corrections Act, but its reading is unsupportable for the reasons laid out below. Accordingly, JFCR's motion to dismiss should be granted.

B. Biogen Misinterprets AIA § 3(n)(1).

Section 3 of the AIA contains two different types of provisions. Some address systemic changes to the patent laws and procedures, such as the creation of the Patent Trial and Appeal Board. The change in the availability of review falls into this category. Other provisions apply to the assessment of a particular patent or patent application. For example, AIA §§ 3(b) and 3(c), 125 Stat. 285-287, set forth the "conditions for patentability" under the new first-inventor-to-file system, addressing novelty, prior art, and non-obvious subject matter.

Section 3(n)(1) specifies the effective date for all of Section 3. It reads as follows:

> Except as otherwise provided in this section, **the amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act**, and shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time

> (A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the effective date described in this paragraph; or
>
> (B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

AIA § 3(n)(1), 125 Stat. 293 (emphases added).

Biogen argues that this section shows that *all* provisions of Section 3 only apply after March 16, 2013 (i.e., eighteen months after the effective date of the AIA) and "only to those patent applications and issued patents, that contain claims to inventions that have an effective filing date on or after March 16, 2013." However, Biogen ignores the preamble qualification "[e]xcept as otherwise provided in this section . . . ." Biogen also confuses the bolded and underlined portions above. *First*, the bolded portion of the of 3(n)(1) sets forth the effective date of Section 3 as a whole: eighteen months after the effective date of the AIA, i.e. March 16, 2013. *Second*, the underlined portion of 3(n)(1) above specifies that those portions of Section 3 that apply to particular patents and patent applications apply only to those applications with an effective filing date on or after March 16, 2013. But only some of the amendments in section 3 are directed towards particular patents or patent applications. Other amendments make global changes to the patent system, and as to those amendments, the underlined portion of 3(n)(1) is irrelevant and has no effect.

An example illustrates the application of 3(n). Section 3(b) begins, "A person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication [or other conditions]. . . ." Section 3(b) is directed toward individual patent applications or patents, and so it makes sense to apply 3(n)(1)(A) and (B). Section 3(j), on the other hand,

amended 35 U.S.C. § 146 and thus deals with *decisions* of the Board, not particular patents or patent applications. Sections 3(n)(1)(A) and (B) are therefore not implicated.

To interpret § 3(n) otherwise results in absurdity. It cannot be, for example, that the definitions provided in § 3(a) change depending on the date of the patent or patents involved. Indeed, § 3(a) defines the term "effective filing date" that is later used in § 3(n)(1)(A) – so if determining whether the definitions in § 3(a) were in force required consulting § 3(n)(1)(A), the statute would become hopelessly circular. But perhaps most importantly here, the idea that § 3(j) is sometimes not in effect, and that therefore the pre-AIA version of 35 U.S.C. § 146 sometimes remains in force, creates a ludicrous result. The pre-AIA version of 35 U.S.C. § 146 allows for appeals of the "decisions of the Board of Patent Appeals and Interferences," but that Board was abolished by the AIA, and therefore ceased to exist as of September 16, 2012. Section 146 thus *cannot* remain in force for interferences declared after that date, as Biogen would have it, because it would create a system for appealing the decisions of a non-existent body. Rather, § 3(j), with its jurisdiction-stripping provisions, must come into force and remain in force on the date indicated by the plain text of § 3(n)(1): March 16, 2013.

C. Biogen's Argument Renders AIA Section 6(f)(3)(c) and the Technical Corrections Act Superfluous

Even if section 3(n)(1) were unclear, the rest of the statute makes clear that Biogen's interpretation cannot be correct. That is because Biogen's argument renders AIA § 6(f)(3)(c) (and portions of the Technical Corrections Act, *see infra*) superfluous. As explained above, § 6(f)(3)(c) restores the right of appeal to the district court *and* Federal Circuit for parties to patent interferences that were decided on or before September 16, 2012. If Biogen were correct that the pre-AIA version of 35 U.S.C. §§ 141 and 146 remained in effect for any patent with all claims

predating March 16, 2013, there would have been no reason to include § 6(f)(3)(c). Indeed, as § 6(f)(3)(c) deals with appellate jurisdiction over interferences commenced before **September 16, 2012**, it by definition will apply to patents with claims effective before **March 16, 2013**. If Biogen's argument were correct, then, section 6(f)(3)(c) would have been unnecessary.

Similarly, the Technical Corrections Act § 1(k)(3) would be superfluous under Biogen's reading. According to Biogen, the path of review for an interference like this one – involving patents and/or applications filed in the 1990s, but declared in the summer of 2013 – would be governed by the pre-AIA version of 35 U.S.C. §§ 141 and 146. But by its plain terms, § 1(k)(3) of the Technical Corrections Act governs review of "interference proceedings that are declared after September 15, 2012," and explicitly provides for *only* Federal Circuit review of such decisions under § 141. Biogen fails to explain why Congress would have affirmatively corrected the statute to provide this path for review if the pre-AIA version of §§ 141 and 146 already provided a path to review for decisions on such interferences. And, again, it is difficult to discern when the Technical Corrections Act section 1(k)(3) would come into force at all under Biogen's version of the statute. Interferences may only be declared with respect to patent applications filed before March 16, 2013; but according to Biogen, no provision of § 3 of the AIA comes into force except with respect to patents or applications with claims with effective dates *after* March 16, 2013. It violates the core principles of statutory interpretation that Congress enacted so many provisions with no effect whatsoever. *See TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.") (internal quotation marks and citations omitted).

D. None Of The PTO's Statements Create Subject-Matter Jurisdiction In This Court

Biogen argues that various regulations of the PTO show that there is subject-matter jurisdiction in this Court. Even leaving apart the most obvious response – that the PTO can hardly confer jurisdiction if Congress chose not to do so – Biogen is wrong. The PTO has not taken a position on whether a district court can hear appeals of decisions in interferences, and Biogen must selectively edit the PTO's statements to suggest otherwise. And, in any event, the PTO is only entitled to make regulations that "govern the conduct of proceedings *in the Office*," 35 U.S.C. § 2(b)(2)(A), and those regulations must be "not inconsistent with the law," 35 U.S.C. § 2(b)(2). Hence, even if the PTO's regulations did support Biogen's theory, that would be irrelevant here.

Biogen chiefly relies on the PTO's commentary on its proposed rule 90.1, published on August 14, 2012, under the heading "Part 90—Judicial Review of Patent Trial and Appeal Board Decisions." 77 Fed. Reg. 48612. The PTO began its commentary by noting that the PTO had repealed its old rules concerning appellate review, 37 C.F.R. §§ 1.301 to 1.304, "in favor of directing the reader to the relevant statutory provisions." 77 Fed. Reg. at 48625. It did so in part to "avoid undue public reliance on the Office's paraphrase of statutory text." *Id.* In discussing the scope of its new rule, the PTO explained that "to *the extent that an interference proceeding under 35 U.S.C. 135 is available and judicial review of that decision is available*, the Office will continue to apply the regulations as they existed when the AIA was enacted (or as subsequently modified prior to July 1, 2012) to those proceedings. . . ." *Id.* (emphasis added). The PTO's commentary is thus appropriately agnostic, only stating that it would apply pre-AIA rules "to the extent that . . . judicial review of [a] decision is available." The PTO was not, in this publication,

taking a position on *whether* such review is available. Its caution was highlighted by the following sentence of its commentary discussing section 6(f)(3)(c), the provision that Biogen would reduce to surplusage, which states neutrally that "certain interferences *may* be deemed to be eligible for judicial review as though they were derivation proceedings." *Id.* (emphasis added).

The PTO's respect for its role is also clear from the final text of rule 90.1. It reads, in full:

> The provisions herein govern judicial review for Patent Trial and Appeal Board decisions under chapter 13 of title 35, United States Code. Judicial review of decisions arising out of inter partes reexamination proceedings that are requested under 35 U.S.C. 311, and *where available*, judicial review of decisions arising out of interferences declared pursuant to 35 U.S.C. 135 continue to be governed by the pertinent regulations in effect on July 1, 2012.

37 C.F.R. § 90.1 (emphasis added). The italicized language was conveniently absent from Biogen's reproduction of Rule 90.1 in its opposition brief, but it makes clear that the PTO correctly defers to the AIA provisions on the availability of judicial review.

Biogen further puzzlingly claims that one of the "pertinent regulations in effect on July 1, 2012" that the PTO will apply under rule 90.1 is 37 C.F.R. § 1.303, which provided for district court review of an interference decision under 35 U.S.C. § 146. But that section was "removed and reserved" effective September 16, 2012, before the declaration of the interference at issue. *See* 37 C.F.R. § 1.303; *see also* 77 Fed. Reg. at 48669. Hence, it cannot provide an avenue for district court review for Biogen.

III. CONCLUSION

For the foregoing reasons, Biogen's complaint should be dismissed for lack of subject matter jurisdiction.

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Respectfully Submitted,

/s/ Elisabeth M. Oppenheimer

Elisabeth M. Oppenheimer, MA 686312
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6757 (t)
(617) 526-5000 (f)
elisabeth.oppenheimer@wilmerhale.com

Nels T. Lippert, *Pro Hac Vice*
Tarter Krinsky & Drogin LLP
1350 Broadway
New York, NY 10018
(212) 216-1157 (t)
(212) 216-8001 (f)
nlippert@tarterkrinsky.com

S. Calvin Walden, *Pro Hac Vice*
Paula Estrada de Martin, *Pro Hac Vice*
Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
New York, NY 10007
(212) 230-8800 (t)
(212) 230-8888 (f)
calvin.walden@wilmerhale.com
paulaestradademartin@wilmerhale.com

Counsel to Defendant Japanese Foundation for Cancer Research

CERTIFICATE OF SERVICE

I certify that on April 24, 2014, I electronically filed the foregoing Reply with the Clerk of Court by using the CM/ECF system, which provided an electronic notice and electronic link of the same to all attorneys of record.

/s/ Elisabeth M. Oppenheimer

Elisabeth M. Oppenheimer